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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|-----------------------|------------------|
| 10/553,600                  | 10/18/2005  | Haruhiko Komoriya    | 038788.56807US        | 6021             |
| 23911                       | 7590        | 01/09/2008           | EXAMINER              |                  |
| CROWELL & MORING LLP        |             |                      | CHANDRAKUMAR, NIZAL S |                  |
| INTELLECTUAL PROPERTY GROUP |             |                      |                       |                  |
| P.O. BOX 14300              |             |                      | ART UNIT              | PAPER NUMBER     |
| WASHINGTON, DC 20044-4300   |             |                      | 1625                  |                  |
| MAIL DATE                   |             | DELIVERY MODE        |                       |                  |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                   |                     |
|------------------------------|-----------------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>            | <b>Applicant(s)</b> |
|                              | 10/553,600                        | KOMORIYA ET AL.     |
|                              | Examiner<br>Nizal S. Chandrakumar | Art Unit<br>1625    |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3 and 15-18 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 and 15-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____.                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____.                         |

**DETAILED ACTION**

This application 10/18/2005 is a 371 of PCT/JP04/04007 03/24/2004.

Claims 1-3 and 16-18 are pending.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

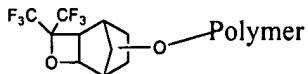
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 15 are drawn to ~~all~~ alcohols that are 'partially or entirely' protected. It is unclear what a partially protected alcohol is. An alcohol is either protected or not protected. Further, the term protection in general, refers to a chemistry strategy that relates to groups that is present 'temporarily' in the course of a chemistry synthetic sequence. In this context, the groups defined as 'protecting' are ethers many of each can not be 'removed' given the overall structures of the monomer and the intended polymers. It is suggested that the applicant provide specific definition of the groups.

Claim 16 is drawn to polymers and copolymers without defining the 'repeat units' in these polymers. As such it is vague what the applicant is seeking protection for. Further the claim language is ambiguous because it is unclear what is being polymerized. Based on what is disclosed in the specification, the monomer compound that is polymerized or copolymerized does not have the structure of compounds of claim 1. Compounds of claim 1 are starting materials for making polymerizable monomers.

It is suggested that Claim 16 is rewritten to include the polymer/copolymer structure along the following lines:



***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a limited number of fluorinated monomers and polymers, does not reasonably provide enablement for the plurality of possible structures claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. For example, the specification is enabling for R1=R3=R6=R4=H and there is one example wherein R2 is other than H. The direction and guidance present for these compounds are incompatible for other variables claimed.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art.

All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: The claims are drawn to five independently varying variables, many of which are vaguely defined rendering the number of conceivable structures large.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability (see below) in the art of organic chemistry, it is noted that each embodiment of the invention is required to be individually assessed for viability.

The amount of direction provided by the inventor and the presence or absence of working examples: The direction and working examples is limited to two examples (and their antipodes) with respect to compounds of claims 1-3 and 15. Guidance for making protected derivatives of claim 15 is not seen in the specification, especially in view of the unpredictability with regards to the viability of commonly used alcohol protecting groups for hexafluorocarbinol hydroxyl group because of its unusual pKa.

The regiochemical outcome of homo Diels-Alder type reaction used for making compounds of claim 1, depends on the interplay of steric bulk as well as other electronic factors of the 'dienophile' component (hexafluoroacetone). Likewise, the 'solvolytic' type rearrangement to form the oxetane ring and the installment of the linker arm to attach the polymerizable group depends on the substituents. Examples for these factors causing uncertainty are found in the specification itself: Examples 6 illustrates the limitation with respect to formation of claimed compounds of claim, i.e., only one regio-isomer is formed. See Example 3 for the regiospecificity with regards to the monomer formation dictated by steric hindrance. See Example 2 for the regiospecificity, and Example 7 for the lack of regiospecificity in the formation of oxetane ring. Example 8 illustrates the uncertainty with regards to positioning of the linker arm. Such factors limit the number of possibilities for the variables. Further, for mechanistic reasons, variables such as OH, haloalkyl, and halo groups in the compounds of claims 1 and 15 would interfere with the above-indicated formation of oxetane ring.

The specification does not provide citations (commercial or literature) for procuring the starting materials usable that could substitute for the lack of working examples with respect to non-enabled claimed possibilities for R1=R3=R6=R4=H. Methods for introduction of these groups subsequent to the formation of the teracycle (compounds of claim 1) are also not disclosed in the specification.

The polymerizable group is limited, at least, to the extent that the linker is attached to the oxetane

containing tricycle by Oxygen atom (see rejection under 35 U.S.C. 112 second paragraph). This is because the specification is enabling only for 'solvolytic' type reaction for introducing the polymerizable linker arm.

There is no example, guidance or direction in specification, for polymerization or copolymerization wherein the monomer is generated *in situ* from the compounds of claim 1 (see rejection under 35 U.S.C. 112). For this reason, claim 16 should be amended along the lines of the suggestion (see rejection under U.S.C. 112 second paragraph).

The quantity of experimentation: For the reasons presented above, in order to utilize the invention as claimed, that is to make and use the claimed compounds, the skilled artisan would be presented with an undue amount of experimentation. The instant disclosure is broad and generic.

With regards to claim 1, the specification is enabling for R1=R2=R3=R6=R4=H and R1=R3=R6=R4=H and R2 = hexafluorocarbinol.

With regards to claim 3, enablement is present for compounds 7 and 8.

Compounds of claim 2 and compounds 7 and 8 of claim 3 are free of prior art.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 15-16 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 11/941433. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both the applications are drawn to the same precursors to the monomer as well as to the same polymers and copolymer of the monomers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 17 and 18 are objected to as depending on a rejected base claims but would be allowable if rewritten to overcome the rejections under USC 112-2 and the double patenting rejections set forth in this office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nizal S. Chandrakumar whose telephone number is 517-272-6202. The examiner can normally be reached on 8.30 am – 5 pm Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867 or Primary Examiner D. Margaret Seaman can be reached at 571-272-0694. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*nc*  
Nizal S. Chandrakumar

*M.S.*  
D. MARGARET SEAMAN  
PRIMARY EXAMINER